

## REMARKS

Previously pending claims, Claims 1, 4-7, 9, 10, 13-16 and 19-21 were all rejected on various grounds.

Applicants thank Examiner Davis and Ungar for the courtesy of an interview conducted on June 15 2005. This interview helped clarify several outstanding issues, particularly (a) the new § 102/103 rejections and its "limitation" to only one relevant compound recited in the claims (and (b) the § 112 rejection for lack of adequate written description of a genus of small molecule MEK inhibitors. The present amendments are responsive to the Office's position concerning both these issues.

The claims are amended to incorporate limitations from certain dependent claims into independent claims (claim 4 into claim 1; claim 13 into claim 9; claim 19 into claim 16) accompanied by cancellation of the now-extraneous dependent claims.

It is submitted that no new matter has been introduced by the present amendments and entry of the same is respectfully requested. Applicants respectfully submit that their application is now in condition for allowance.

### **I. Priority Date**

The Office maintained its assertion that priority date of claims drawn to a method of killing melanoma, using PD184352, such as claims 4, 5, 13, 14, 19, 20, should be **08/31/2001**, since the prior application 60/229,290 filed on 09/01/2000 did not recite PD1 84352, and the data provided by applicant concerning claiming benefit of 60/285690, filed on 04/24/2001 were not consistent with PTO records.

The Office is invited to examine the first provisional application, Serial No. 60/229,290 from which this case claims priority (filed 09/01/2000), where the following language appears at page 18, line 28 to page 19, line 4 (emphasis added):

Other small molecule inhibitors of the MAPK pathway are known to be, or are expected to be, cytotoxic to melanoma cells. These include the **MEK inhibitors PD184352** (Parke-Davis) (Sebolt-Leopold, JS *et al.*, *Nature Med.* 5:810-816 (1999)) and **U0126** (DuPont) (Favata, M *et al.*, *J Biol. Chem.* 273:18623-18632 (1998)), the p38 kinase inhibitor SB 203580 (Schering-Plough) (Cuenda, A *et al.*, *FEBS Lett.* 364:229-233 (1995)), and the like.

The undersigned showed this document and this citation to Examiner Davis during the interview.

Based on the foregoing, the correct priority date of the present claims should be accepted as 09/01/2000,

**II. Rejections Under 35 U.S.C. § 112, First Paragraph - Written Description**

The Examiner maintained the rejection of claims 1, 7, 9-10, 16 due to lack of “a clear written description of an organic small molecule inhibitor of MAPK/ERK kinase enzymes” for reasons of record.

Applicants have amended the independent claims 1, 9 and 16 by incorporating the limitations of 4, 13 and 19, respectively (species of MEK inhibitors) while excluding the compound U0126 as described below.

Applicants therefore request that the Office remove this ground for rejection for the presently amended claims.

**III. Rejection Under 35 U.S.C. § 112, First Paragraph - Lack of Enablement**

The Office maintained rejection of claims 1, 4-5, 7, 9-10, 13-14, 16, 19-20 for lack of enablement of a method of killing melanoma for reasons of record.

Applicants believe the aforementioned amendments render this ground for rejection moot, and request that the Office remove this ground for rejection.

**IV. NEW PRIOR ART REJECTIONS**

The Office rejected Claims 1 and 4 under 35 USC 102(a) as being anticipated by Shellman Y et al, April 2000, *J. Investig. Dermatology*, 114(4):789 (abstract only) which listed in its meager disclosure the compound U0126 as possibly inducing apoptosis in melanoma cells. This reference was combined with three other references to reject all the claims as being obvious under § 103(a).

This issue was discussed extensively in the interview. Applicant pointed out that this reference does not indicate which of the several compounds it lists acted alone directly to induce apoptosis in melanoma cells (vs. acting only in combination with cisplatin to achieve this effect). Given this fundamental ambiguity, Applicants believe that this reference should be withdrawn for all pending grounds of rejection. The Examiners, however, asserted that, in view of Applicants’ teachings, this rejection should stand under § 102 (although not under § 103) because the U0126 compound inherently would be expected to have the capacity to induce apoptosis of melanoma cells. Because this rejection would rely totally on an assertion of inherency, the Examiners indicated that

the § 103 rejections would not be applicable. Although Applicants do not agree with the Office's position regarding the Office's view that the indicated claims are anticipated by this reference, in order to advance prosecution, they have withdrawn the reference to the compound U0126 from the pending claims.

Thus, the present claims are free of the cited prior art, and the rejection may properly be withdrawn.

V. **CONCLUSION**

In conclusion, it is respectfully requested that the above amendments, remarks and requests be considered and entered. Applicant respectfully submits that all the present claims are in condition for allowance, and respectfully requests early notice of such favorable action.

Fees for the extension of time may be charged to the **Deposit Account 50-0911**. . In the unlikely event that the Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due to **Deposit Account 50-0911**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: June 20, 2005



Samuel Livnat.

Registration No. 33,949

Direct Line: (202) 496-7845

MCKENNA LONG & ALDRIDGE LLP

1900 K Street, N.W.

Washington, DC 20006

Telephone: (202)-496-7500

Telefax: (202) 496 7756

Attorneys for Applicant